**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ALABAMA**
**NORTHEASTERN DIVISION**

| | | |
|---|---|---|
| **VINTAGE PHARMACEUTICALS, INC.,** | } | |
| **Plaintiff,** | } | |
| **v.** | } | **Case No.: CV 01-P-1847-NE** |
| **WATSON PHARMACEUTICALS, INC.; HALSEY DRUG COMPANY, INC.,** | } | |
| **Defendants.** | } | |



## MEMORANDUM OF OPINION

This case is before the court on Defendant Watson Pharmaceuticals, Inc.'s ("Watson") Motion for Summary Judgment (Doc. #48). The motion is directed to the claim of Plaintiff, Vintage Pharmaceuticals, Inc. ("Vintage"), that Watson breached a Supply Agreement which existed between the parties.[1] The court has reviewed the evidentiary materials submitted by Watson in support of summary judgment (Doc. #49). Likewise, the court has reviewed Vintage's opposition (Doc. #52) and evidentiary materials submitted in opposition to Watson's motion. (Doc. #53). The court heard oral argument on the motion on March 17, 2004. There are no disputed issues of material fact, no substantial evidence of a contract breach, and Watson has demonstrated it is entitled to judgment as a matter of law. Therefore, Watson's motion is due to be granted.

## PIONEER AND GENERIC DRUGS

A proper understanding of some of the issues in this case begins with a review of certain congressional actions in the area of the manufacture of generic drugs. The Food, Drug and Cosmetic

[1]The original agreement was between Vintage and Oclassen Pharmaceuticals, Inc. However, Watson is the successor in interest of Oclassen.

Act regulates the entry of new pharmaceutical products into our nation's marketplace. *See* 21 U.S.C. §§ 301, *et seq*. Before the marketing of a new drug can take place, the Food and Drug Administration ("FDA") must approve the product. *See id.* § 355(a). The company seeking such approval must submit a New Drug Application ("NDA"). *Id.* The product of the successful initial applicant is often referred to as the "pioneer drug." *See Andrx Pharms., Inc. v. Biovail Corp. Int'l.*, 256 F.3d 799, 801 (D.C. Cir. 2001). In considering NDAs, the FDA requires a thorough, lengthy, and costly process that includes clinical studies regarding the drug's safety and effectiveness. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). In 1984, Congress became concerned that NDA submission and approval was a "cumbersome drug approval process [that] delayed the entry of relatively inexpensive generic drugs into the market place." *Mylan Pharms. Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000). Accordingly, Congress enacted the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L.No. 98-417, 90 Stat. 1585 (1984) (codified in various sections of Titles 21, 35 and 42 U.S.C.) The Hatch-Waxman Amendments simplified the approval process for generic versions of already-approved pioneer drugs.

There are at least two different and important aspects of this simplified approval process that are significant for purposes of this case. First, generic drugs are "versions of brand name prescription drugs that are often sold without a brand name and that contain the same active ingredients, but not necessarily the same inactive ingredients, as the original." *United States v. Generix Drug Corp.*, 460 U.S. 453, 455 (1983). Second, under the Hatch-Waxman Amendments, an applicant seeking to introduce generic drugs into the market place is no longer required to file a complete NDA. Rather, an Abbreviated New Drug Application ("ANDA") process is submitted.

The generic applicant may rely on the clinical findings of the pioneer drug. *See* 21 U.S.C. § 355(j)(2)(A). The most significant showing that an ANDA applicant must make is that the generic is "bioequivalent" to the brand version. In the words of Congress, it must be demonstrated that the "new drug can be expected to have the same therapeutic effect as the listed drug . . . ." *Id.* § 355(j)(2)(A)(iv); *see also id.* §§ (j)(8)(B)(i)-(ii). With this framework in place, the court will address the facts that are undisputed in the record before it.

**UNDISPUTED FACTS**

This case arises from a dispute over a Supply Agreement executed in February 1995. Vintage had previously acquired the NDA for Monodox. Monodox is the branded name for the drug manufactured under NDA 50-641, an application approved by the FDA for the manufacture of a doxycycline monohydrate pharmaceutical. Vintage entered into the Supply Agreement with a company known as Oclassen. Defendant Watson subsequently acquired Oclassen and thus became the successor in interest to the Supply Agreement.

Vintage alleges that Watson breached paragraph 7(c) of the contract by not purchasing from it "the required amount of drug product according to the terms" of the Supply Agreement. Paragraph 7(c) of the Supply Agreement provides in pertinent part:

> During the term of this agreement, [Defendant] agrees to purchase from Vintage a minimum of eighty percent (80%) of [Defendant's] requirements for Product capsules in each calendar year.

Supply Agreement ¶ 7(c). The term "Product" is defined in the Supply Agreement as follows:

> 'Product' shall mean the compound known as doxycycline monohydrate in dosage forms of 50 mg and 100 mg capsules, the chemical composition of which is attached hereto as Exhibit B, as manufactured in accordance with the NDA specifications, and meeting the Internal Guidelines for Acceptance.

Supply Agreement ¶ 1(v). Other provisions in the contract define what is meant by the term NDA specifications:

> 'NDA' shall mean the approved NDA 50-641 for 50 mg and 100 mg doxycycline monohydrate capsule products.
>
> 'NDA Specifications' shall mean the Finished Product Specifications contained in the NDA which are the minimum specifications which the Products must meet throughout the Product's shelf-life.

Supply Agreement ¶¶ 1(r) & (s). Thus, Watson maintains that in order to be Product under the Supply Agreement, the doxycycline monohydrate product must meet at least two criteria. First, it must be manufactured in accordance with the specifications contained in NDA 50-641. Second, it must consist of the same chemical composition as that specified for Product in the Supply Agreement. With that caveat, Watson claims that it has not breached the Supply Agreement and further has purchased and continues to purchase 100% of its requirements for Product, as defined by the Supply Agreement, from Vintage.

Watson has another supplier of doxycycline monohydrate, Halsey Pharmaceuticals, Inc. ("Halsey"). Halsey sells a generic version of Monodox manufactured in accordance with ANDA 65-041,[2] not NDA 50-641, which is specified in the agreement. The Halsey drug has a different chemical composition than that specified by the Supply Agreement. The differences, however, do not relate to the active ingredients in the two doxycycline monohydrate drugs. Those are the same. It is the inactive ingredients in Monodox and the generic drugs that are dissimilar.

---

[2]The FDA approved the ANDA for the Halsey drug pursuant to the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act.

## STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The party asking for summary judgment always bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of the pleadings or filings which it believes demonstrate the absence of a genuine issue of material fact. *See id.* at 323. Where, as here, the moving party does not have the burden of proof at trial and meets its initial responsibility, Rule 56(e) requires the non-moving party to go beyond the pleadings and by his own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial. *See id.* at 324.

## DISCUSSION

The key questions here, as is the case in most contract dispute litigation, are what did the contract require and was there a breach of the agreement. Vintage claims that its Monodox product and the Halsey generic, manufactured under the ANDA, are the same for purposes of the Supply Agreement. That is, it claims that the doxycycline monohydrate capsules purchased by Watson from Halsey (i.e., the generic product) meet the definition of Product under Paragraph 7(c), as defined by paragraph 1(v) of the agreement. Vintage concedes that the Halsey drug has a different chemical composition than that specified by the Supply Agreement. However, it contends that the difference between the Vintage and Halsey products is limited to the fact that the two drugs do not contain the

same inactive ingredients.[3] According to Vintage, the two drugs possess the same active ingredients; and the different inactive ingredients have no impact on their efficacy. Thus, according to Vintage, the Halsey product, like its own, meets the definition of Product. The court disagrees.

The agreement requires the court to look to North Carolina law to interpret it. *See* Supply Agreement ¶ 29. The parties agree that North Carolina law, in the form of the parol evidence rule, prohibits this court from considering extrinsic evidence where a contract is clear and unambiguous. *See e.g.*, *Phelps v. Spivey*, 530 S.E. 2d 82, 86-87 (N.C. App. 2001). Similarly, the existence of a merger or integration clause, such as the one that exists in the Supply Agreement (*see* Supply Agreement ¶ 26), renders the parties' previous negotiations null and void. *See Clifford v. River Bend Plantation, Inc.*, 323 S.E. 2d 23, 25 (N.C. 1984).

The court has reviewed the Supply Agreement and finds that it is not ambiguous. Vintage's President and CEO, William Propst, Sr., testified in his deposition that the Supply Agreement was clear and unambiguous when he signed it in 1995. Although the determination of whether a contract is ambiguous is actually a question of law for the court, a review of the contract demonstrates that Propst's testimony is correct. The definition of the term Products is straightforward, and the court need look no further than the four corners of the contract to interpret its meaning and requirements. Accordingly, Vintage's various arguments that rely upon extrinsic evidence (*e.g.*, the assertion that a contemporaneous agreement related to the sale of the NDA for Monodox shows that the term Product should be read more expansively than the text of Paragraph 1(v)) cannot be considered.

---

[3]The inactive ingredients that may be different in a brand name product and a generic include fillers, lubricants, and dyes used to create the dosage form.

Likewise, the court has reviewed the parties briefs on the issue and finds the Supply Agreement is not latently ambiguous. Under North Carolina law, "a latent ambiguity may arise where the words of a written agreement are plain, but by reason of extraneous facts the definite and certain application of those words is found impractical." *Miller v. Green*, 112 S.E. 417, 417 (N.C. 1922); *see also Jefferson Pilot Life Ins. Co. v. Smith Helms Mulliss & Moore*, 429 S.E. 2d 183, 185 (N.C. App. 1993). That state's latent ambiguity doctrine is frequently applied in the context of a misidentification of a parcel of land that was the subject of a contract. *See e.g.*, *Gilbert v Wright*, 141 S.E. 577, 578 (N.C. 1928); *River Birch Assoc. v. City of Raleigh*, 388 S. E. 2d 538, 551 (N.C. 1990); *Redd v. Taylor*, 153 S.E. 2d 761, 766 (N.C. 1967).

This is not a case of impracticability or misidentification, and the doctrine of latent ambiguity does not apply here. The term Product is unambiguously defined in the Supply Agreement as being manufactured according to a specific NDA and composed of a specific chemical composition. *See* Supply Agreement ¶ 1(v). Plaintiff has not pointed to any extraneous facts that make the agreement impractical. These facts unequivocally show that there simply is no latent ambiguity as to the contract, in general, or the definition of Product in the Supply Agreement, in particular. Further, the court finds (and Propst admitted) that the Agreement, which has a merger/integration clause, was clear and unambiguous at the time the parties entered into it. *See* Propst Dep. at 14:10-22.

Apart from the question of ambiguity, Vintage asserts various arguments in opposition to Watson's motion. First, Vintage argues that the Halsey generic drug meets the definition of "Product" under the Supply Agreement. That assertion is simply unsupported by the contract's language. The agreement defines "Products" in Paragraph ¶ 1(v).

> 'Products' shall mean the compound known as doxycycline monohydrate in dosage forms of 50 mg and 100 mg capsules, the chemical compound of which is attached

> hereto as Exhibit B, as manufactured in accordance with the NDA specifications, and meeting the Internal Guidelines for Acceptance.

(emphasis added). The Halsey drug (1) has a different chemical compound than Vintage's and (2) was manufactured in accordance with ANDA 65-041 specifications, not those of NDA 50-641.

Second, Vintage argues that the drugs are the same because the differences in them have nothing to do with their active ingredients. But that is of no consequence to this dispute because the contract's requirements – and consequently the obligations of Watson – do not turn on the similarity in the drugs' active ingredients. This is the case for at least two reasons. First, the definition of Product found in Paragraph 1(v) provides that for a drug to be Product it must have the same chemical compound as reflected in Exhibit B to the agreement and be manufactured pursuant to the NDA 50-641 specifications. Second, as Vintage points out, when the parties wished to refer to doxycycline products other than those defined by paragraph 1(v) of the agreement, they employed different language in a separate provision of the agreement. *See, e.g.*, ¶ 3(b) (prohibiting Vintage from selling "Products, Commercial Product, or any other doxycycline monohydrate product" to anyone other than Watson) (emphasis added).

Third, Vintage's argument that the drugs are the same because they are bioequivalent is also wide of the mark. Any generic drug manufactured under an ANDA must be the bioequivalent of the predecessor pioneer drug. *See* 21 U.S.C. §§ 355(j)(2)(A) & (8)(B). But the contract's language makes no reference to bioequivalence. As the Halsey drug neither possesses the same chemical composition nor is manufactured in accordance with NDA 50-641 specifications, it is not Product within the meaning of the Supply Agreement. Therefore, Watson was free to purchase the Halsey drug without violating the Supply Agreement with Vintage, and Watson's proof that it has purchased "100% of its requirements for Product capsules" is undisputed. Vintage has failed to present

substantial evidence that Watson breached the Supply Agreement.

Fourth, Vintage argues that the language contained in the agreement's definition of Product – including the incorporation of the chemical composition in Exhibit B and the requirement that the drug be manufactured in accordance with NDA 50-641 – is more properly regarded as warranties. The plain language of the agreement, both in paragraph 1(v) and the contract as a whole, simply does not permit such an interpretation. *See Gilbert*, 141 S.E. at 577 ("A contract must be construed in its entirety.") The first section of the Supply Agreement addresses the definitions of a number of terms used in the contract. *See* Supply Agreement ¶ 1(a)-(x). By contrast, in paragraph 16 of the agreement, Vintage makes certain representations and warranties to Defendant. The fact that chemical composition information and NDA manufacture specifications are included in the definition of Product must be read to mean that a drug, in order to be Product, must meet those requirements. *See Woods v. Insurance Co.*, 246 S.E. 2d 773, 777 (1978) ("Where a [contract] defines a term, that definition is to be used.")

Finally, perhaps the most compelling indication that the Halsey generic is not Product within the meaning of the Supply Agreement is this: At oral argument, Vintage's counsel conceded that under the contract, as well under NDA 50-641, it could not manufacture and/or sell the generic drug Watson has purchased from Halsey. Accordingly, as a matter of law and logic, it follows that (1) the Halsey's generic drug is not "Product" under Paragraph 1(v) of the agreement; and (2) Watson's purchase of the generic from Halsey could not – and did not – violate paragraph 7(c) of the contract. *See also* Propst Dep. at 51: 23-52:3.

For the reasons stated above, Watson's motion for summary judgment is due to be granted. The court has also reviewed Watson's motions to strike the affidavits of Propst and Timothy

Covington. (Docs. ## 57-58). Both motions are due to be denied.[4]

**DONE** and **ORDERED** this 12th day of April, 2004.

**R. DAVID PROCTOR**
UNITED STATES DISTRICT JUDGE

[4]As already stated, the court agrees with the testimony of Propst and the position of Watson that the contract is clear and unambiguous. To the extent that Propst's affidavit presents parol evidence regarding the Supply Agreement, or assertions about how the contract should be interpreted that are not based upon the contract language, the court has disregarded such evidence and/or assertions. The court has also reviewed Covington's affidavit. Although Covington strives mightily to explain why the differences in the Vintage and Halsey drugs are not significant, his affidavit itself demonstrates at least two points: there are differences between the drugs and the Halsey drug does not meet the definition of "Product" found in the Supply Agreement.